Microaire Surgical Instruments, LLC
Darren Reeves
Consultant
7305 Hancock Village Dr
Suite 109
Chesterfield, Virginia 23832

June 9, 2021

Re: K113128
Trade/Device Name: Microaire Surgical Instruments Llc
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Darren Reeves:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 17, 2012. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MicroAire Surgical Instruments, LLC
% DP Distribution & Consulting, LLC
Mr. Darren Reeves
Consultant
15637 Fox Cove Circle
Moseley, Virginia 23120

AUG 17 2012

Re: K113128
Trade/Device Name: MicroAire LipoTower System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: July 5, 2012
Received: July 9, 2012

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

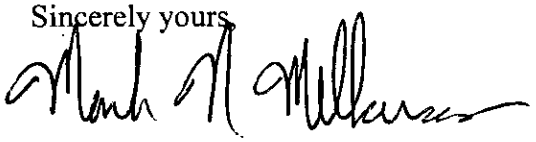
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number known: K113128

Device Name: MicroAire LipoTower System

Indications for Use:

The MicroAire LipoTower System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The MicroAire LipoTower System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

Prescription use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113128

K113128

1 of 4

Section 5: 510(k) Summary

AUG 17 2012

1) Preparation Date: October 12, 2011

2) Submitted by: MicroAire Surgical Instruments LLC
1641 Edlich Drive
Charlottesville, Virginia 22911
Owner/Operator #: 9004658

Contact Person/Prepared by:
Darren Reeves
Phone: (804) 307-7706
Fax: (866) 393-4954
Email: dreeves@dpdconline.com

3) Device Identification:
Trade Name: MicroAire LipoTower System
Common Name: Lipoplasty Suction System
Classification: Lipoplasty Suction System (21 CFR 878.5040, Product Code MUU)

4) Predicate Device: Sound Surgical Technologies LLC - SoundVaser System (K022051)

5) Device Description: The MicroAire LipoTower System is a modular wheeled cart that contains an adjustable vacuum source and a tumescent pump (110/120 VAC, 60 Hz). The vacuum source is a rotary vane type pump that delivers 0-29 inHG vacuum and drives the suction of tissue. The tumescent pump is a peristaltic type that delivers 50-600 ml/min of fluid as required. The system includes a control module with an LCD touch screen for control and status of the system and foot controls for controlling the vacuum pump and tumescent pump. Accessories include a bag holding pole, canister rack and shelves with are included. The system requires a biofilter (non-sterile) on the vacuum inlet and collection canisters (non-sterile - 1200ml and 2000ml) which are available separately.

6) Indications for Use:
The MicroAire LipoTower System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:
- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The MicroAire LipoTower System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

7) Comparison to Predicate:

General Technical Characteristics	Predicate - Sound Surgical Technologies, LLC (K022051)	Proposed device
Indications for use	The MicroAire LipoTower System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired: – Neurosurgery – Gastrointestinal and Affiliated Organ Surgery – Urological Surgery – Plastic and Reconstructive Surgery – General Surgery – Orthopedic Surgery – Gynecological Surgery – Thoracic Surgery – Laparoscopic Surgery The System is indicated for use when the fragmentation, emulsification, and aspiration of soft tissue is desired or subcutaneous fatty tissues for aesthetic body contouring is desired	Same
Size (cm) (H x W x D)	89 x 46 x 43	106 x 56 x 69
Input Power	115 & 230 VAC. 50-60 Hz	115VAC, 50-60 Hz
Handpiece		N/A
Diameter (cm)	2.5	N/A
Length (cm)	17.5	N/A
Transducer	PZT crystal	N/A
Vibration Frequency	36-55 kHz	N/A
Probes		N/A
Material	Titanium alloy	N/A
Diameter (mm)	2.9-3.7	N/A
Length (cm)	7.7-27.0	N/A
Irrigation		
Type	Adjustable Flow	Same
Pump Type	Peristaltic	Same
Flow Rate		50-600ml/min
Suction		
Vacuum	24 in Hg	Adjustable up to 29 in Hg
Pump Type		Rotary Vane
Sterilization	Steam	N/A
Sterilization Validation		N/A
Residuals		N/A
Accessories		N/A
AC Power cord	3 prong, Hosp Grade	Same
Handpiece cable	3 m, silicone	N/A
Footswitch control	Yes	Yes
Collection Canister	1250ml	1200ml, 2000ml
Biofilter	N/A	Yes
Prescription	Yes	Yes
IEC Classification	Class I, Type BF	Class I, Type B

	Predicate Used	MicroAire
IEC EN 60601-1 – Medical Electrical Equipment, Part 1: General Requirements for Safety – 2nd Edition		
Radiated emissions		
CISPR 11 for IEC 60601-1-2 clause 36.201.1	Compliant	Compliant
Conducted emissions		
CISPR 11 for IEC 60601-1-2 clause 36.201.1	Compliant	Compliant
Harmonics		
IEC 61000-3-2 for IEC 60601-1-2 clause 36.201.3.1	N/A	Not applicable (to devices whose voltage < 220V).
Flicker		
IEC 61000-3-3 for IEC 60601-1-2 clause 36.201.3.2	N/A	Not applicable (to devices whose voltage < 220V or line-frequency of 60Hz
ESD immunity		
IEC 61000-4-2 for IEC 60601-1-2 clause 36.202.2		
UL 801-2	Compliant	Compliant to level of 2kV
Air ESD	Unknown	Compliant
Radiated immunity		
IEC 61000-4-3 for IEC 60601-1-2 clause 36.202.3		
UL 801-3	Compliant	Compliant
EFT immunity		
IEC 61000-4-4 for IEC 60601-1-2 clause 36.202.4		
UL 801-4	Compliant	Compliant to level of 1.65kV
Surge immunity		
IEC 61000-4-5 for IEC 60601-1-2 clause 36.202.5		
UL 801-5	Compliant	Compliant
Conducted immunity		
IEC 61000-4-6 for IEC 60601-1-2 clause 36.202.6	Unknown	Compliant
Voltage dips and short-interruptions immunity		
IEC 61000-4-11 for IEC 60601-1-2 clause 36.202.7	Unknown	Compliant.Note: Using 1kVA exclusion of 36.202.7 a)1) for 60% voltage dip
Power-frequency magnetic-field immunity		
IEC 61000-4-8 for IEC 60601-1-2 clause 36.202.8.1	Unknown	Compliant
CAN/CSA C22.2 No. 601.1 - Medical Electrical Equipment, Part 1: General Requirements for Safety – 1st Edition	Compliant	Compliant
UL 60601-1 – Medical Electrical Equipment, Part 1: General Requirements for Safety – 1st Edition	Compliant	Compliant
ASME Y 14.5M-1994 - Mathematical Definition of Dimensioning and Tolerancing	Unknown	Compliant
ISO 10079-1 - Medical suction equipment -- Part 1: Electrically powered suction equipment -- Safety requirements	Unknown	Compliant
ISO 15223-1 - Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	Unknown	Compliant
ISO 13485 - Medical devices -- Quality management systems -- Requirements for regulatory purposes	Unknown	Compliant
ISO 14971 - Medical devices -- Application of risk management to medical devices	Unknown	Compliant
IEC 62304 - Medical device software – Software life cycle processes	Unknown	Compliant

8) Conclusion:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design and tested methods.

9) Similarities/Differences of the proposed device when compared to the predicate:

The data within this submission demonstrates that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S.